4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2021-N-0855]

Medical Devices; Neurological Devices; Classification of the Cerebrospinal Fluid Shunt System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the cerebrospinal fluid shunt system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the cerebrospinal fluid shunt system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on August 22, 2014.

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SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the cerebrospinal fluid shunt system as class II (special controls), which we have determined will provide a reasonable assurance of safety and

effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on November 27, 2012, finding the Medtronic DUET™ External Drainage and Monitoring System (EDMS) not substantially equivalent to a predicate device and not subject to a premarket approval application (PMA). Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On December 21, 2012, FDA received Medtronic Neurosurgery's request for De Novo classification of the Medtronic DUET™ EDMS. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to

establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513 (a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 22, 2014, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 882.5560.[1] We have named the generic type of device cerebrospinal fluid shunt system, and it is identified as a prescription device used to monitor and divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of preventing spinal cord ischemia or injury during procedures that require reduction in central nervous system pressure. A cerebrospinal fluid shunt system may include catheters, valved catheters, valves, connectors, and pressure monitors intended to facilitate use of the shunt or evaluation of a patient with a shunt.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Cerebrospinal Fluid Shunt System Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Pyrogenicity/adverse tissue reaction	Biocompatibility testing, Pyrogenicity testing, Labeling, Shelf-life testing, and Sterility testing
Infection (including meningitis)	Labeling, Sterility testing, and Package integrity testing
Cerebrospinal fluid (CSF) leakage	Labeling, and Non-clinical performance testing

[1] FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

Over- and under-drainage • Spinal headache with and without CSF leakage • Intracranial hemorrhage • Hematoma (e.g., spinal, subdural) • Paraplegia • Foreign body obstruction	Labeling, and Non-clinical performance testing
Procedural/use errors	Labeling

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, cerebrospinal fluid shunt systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the guidance document "De Novo Classification Process (Evaluation of Automatic Class III Designation)" have been approved under OMB control number 0910-0844; the collections of information in 21

CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882--NEUROLOGICAL DEVICES

1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 882.5560 to subpart F to read as follows:

§ 882.5560 Cerebrospinal fluid shunt system.

(a) *Identification*. A cerebrospinal fluid shunt system is a prescription device used to monitor and divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of preventing spinal cord ischemia or injury during procedures that require reduction in central nervous system pressure. A cerebrospinal fluid shunt system may include catheters, valved catheters, valves, connectors, and pressure monitors intended to facilitate use of the shunt or evaluation of a patient with a shunt.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) The device description must include a detailed summary of the device technical parameters, including design configuration, dimensions, engineering drawings, and a list of all components with identification of their materials of construction.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Simulated use testing must be conducted to characterize fluid flow and resistance to leakage; and

(ii) Mechanical integrity testing of all connections must be conducted.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the specified shelf life.

(5) Performance data must demonstrate the sterility and pyrogenicity of patient-contacting components of the device.

(6) The labeling must include:

(i) Contraindications with respect to patients who should not receive a lumbar drain;

(ii) A warning that the device should have 24-hour-a-day availability of trained personnel to supervise monitoring and drainage;

(iii) Instructions on proper device setup, positioning, and monitoring;

(iv) Warnings and precautions to inform the user of serious hazards and special care associated with the use of the device;

(v) A statement that the device is not to be reused, reprocessed, or resterilized when open but unused; and

(vi) Cleaning instructions for the injection sites.

Dated: December 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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